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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/532,682

04/26/2005

Hideo Kawachi

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8726

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EXAMINER

WEBB, WALTER E

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/532,682	<b>Applicant(s)</b> KAWACHI, HIDEO	
	<b>Examiner</b> WALTER E. WEBB	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/26/2005</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where values can vary depending on the basis for their determination, the claimed subject matter may be indefinite. See Honeywell Intl. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that, where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the value is indefinite when the claim fails to concurrently recite the method of measurement used to obtain it). Accordingly, the values recited by instant claims 6 and 7 are incomplete insofar as they do not specify the frame of reference used to measure them, e.g., having a crystallinity of 50% to 90%.

In order to overcome this ground of rejection the examiner recommends a crystallinity of 50% to 90% based on the weight of the crude ergosterol in solution.  
(inserting the parameters by which the weight is measured)

Based on the above reasoning, the instantly claimed percentage values in claims 13, 15 and 16 are indefinite insofar as the total against which they are computed is not provided, e.g., “based on the weight of the crude ergosterol in solution”.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1, 3, 4, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Knol (US 2,536,753).

Knol teaches a method of recovering and purification of sterols. (See col. 1, lines 1-3.) Ergosterol is dissolved in iso-octate; water is added yielding 90% ergosterol precipitate. (See col. 7, lines 29-37.) They mention that ergosterol is isolated from yeast, as per claim 3. (See col. 9, lines 1-8.)

The reference anticipates the claims insofar as it teaches a method of separating ergosterol from a water-insoluble organic solvent by supplying water to said solution and precipitating ergosterol.

2) Claims 1-3, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Bills (US 1,842,929).

Bills teach a method of preparing ergosterol, where ergosterol is extracted from saponification of yeast fat. (See col. 1, lines 37-40, and col. 2, lines 65-92.) Water is added to the saponification mixture to precipitate ergosterol. (See *ibid.*) The water was added to such an extent as not to incomplete precipitation, as per claim 2. (See col. 2, lines 78-87.) The purification process was set forth in application serial number 355,440 also US Patent 1,775,548. (See col. 3, lines 15-20.) The purifying process from that reference demonstrated crystallized product of ergosterol, which amounted to 60% of the original crude ergosterol. (See col. 2, lines 85-97 of US Patent 1,775,548.)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knol (*supra*) as applied to claims 1, 3, 4, 6, and 7 above, and further in view of Bills (*supra*).

Knol, taught above, differs from the instant claim 2 insofar as it is silent as to the phase separation between the water-insoluble organic solvent and water.

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to adjust the water such that no phase separation occurs, motivated by the teaching of Bills that success of precipitation of ergosterol depends on

the correct amount of water (see col. 2, lines 78-87.) Bills teaches that too much water will hold the ergosterol partly in colloidal suspension, while too little water will cause incomplete precipitation. (See *ibid.*)

2) Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knol (*supra*) as applied to claims 1, 3, 4, 6, and 7 above, in view of Bills (*supra*) and in further view of Nimberger et al., (US 5,498,138).

Knol, differs from the instant claim 5 insofar as it does not teach wherein the water supply is conducted by continuously or intermittently moisturizing a gas phase portion within an apparatus for precipitating ergosterol.

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to supply water as in claim 5, motivated by the teaching of Bills that correct amount of water is important for precipitation. Claim 5 describes supplying water through a fluid regulator, which monitors the amount of water administered. See Nimberger et al. at abstract for example of fluid regulator. It would have been obvious to use the fluid regulator to ensure that the right amount of water is used for the precipitation of ergosterol from the organic solution of Knol. Such a device would be useful in an apparatus for mass production of ergosterol.

3) Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bills (*supra*) as applied to claims 1-3, 6 and 7 above, in view of Nimberger et al., (US 5,498,138).

Bills, differs from the instant claim 5 insofar as it does not teach wherein the water supply is conducted by continuously or intermittently moisturizing a gas phase portion within an apparatus for precipitating ergosterol.

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to supply water as in claim 5, motivated by the teaching of Bills that correct amount of water is important for precipitation. Claim 5 describes supplying water through a fluid regulator, which monitors the amount of water administered. See Nimberger et al. at abstract for example of fluid regulator. It would have been obvious to use the fluid regulator to ensure that the right amount of water is used for the precipitation of ergosterol from the organic solution of Knol. Such a device would be useful in an apparatus for mass production of ergosterol.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WALTER E. WEBB whose telephone number is (571)270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Walter E. Webb  
/Walter E Webb/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612